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10/750,623	12/31/2003	Sue K. DeNise	MM11100-1	4066
<div>7590 10/02/2007 Gray Cary Ware &amp; Freidenrich LLP Suite 1100 4365 Executive Drive San Diego, CA 92121-2133</div>			<div>EXAMINER THOMAS, DAVID C</div>	
			<div>ART UNIT 1637</div>	<div>PAPER NUMBER</div>
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/750,623

Applicant(s)

DENISE ET AL.

Examiner

David C. Thomas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 33-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 33-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/27/2006 10/20/2004</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Applicant's election with traverse of the trait of a bovine subject of tenderness as a species of generic claims 1, 6, 33 and 37 in the reply filed on December 4, 2006 is acknowledged. Applicant's election with traverse of the single nucleotide polymorphism (SNP) of marker MMBT05224 as set forth in SEQ ID NOS: 21645 from the group of SEQ ID NOS: 19473-21982, wherein the nucleotide corresponding to position 300 can be "a" or "c", and SEQ ID NO. 61201 from the group of SEQ ID NOS: 24493-64886 in the reply filed on March 19, 2007 is also acknowledged. Claims 1-7, 14-16, 23-28 and 33-38 read on the elected species and sequences and will be examined on the merits. Claims 8-13 and 17-22 have been withdrawn. Claims 29-32 and 39-100 have been cancelled.

The traversal is on the ground(s) that search burden alone is insufficient grounds for restriction and the SNPs of the present invention are not independent and distinct. This is not found persuasive because first, there is a serious search burden on the examiner to examine the claims as written. For example, claim 1 recites a method for inferring a trait of a bovine subject from a sample of the subject comprising identifying at least one occurrence of at least one SNP corresponding to position 300 of any of 2,510 SEQ ID NOS. Claims 23 and 34 recite a method wherein each target region is within 3,000 or 500,000 nucleotides, respectively, of a SNP corresponding to position 300 of any of 2,510 SEQ ID NOS. The claim encompasses not only every single SNP possible for a span of 1,000,000 nucleotides surrounding position 300 of any one of the 2,510 sequences listed, but it does not even indicate a particular SNP for each location of

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each isolated polynucleotide within the sequence length up to 500,000 nucleotides. The claim therefore encompasses the possibility of billions of sequences within the series and would definitely be a serious search burden on the examiner and the resources of the Office.

Applicant argues that SNPs represent markers to identify particular positions on a chromosome and that the fundamental assumptions that different nucleic acid sequences are independent inventions do not apply to SNPs. The SNPs of the instant invention are indeed independent and distinct. Election of one particular SNP is not an election of species. If this were so, the genus of polymorphisms represents every possible variation which could occur at about 500,000 or less nucleotides from position 300 of any one of SEQ ID Nos: 19473 to 21982. Furthermore, the groups of SNPs are not similarly connected in design, operation, and effect. Although one SNP might be associated with a similar trait as another SNP, they are in no means connected to each other in design, operation and effect. For example, a G to A change at position 300 in one sequence shares no structural relationship with the G to A change at position 300 in a completely different sequence because each of these changes occurs in distinct sequence regions, with distinct effects and with no necessary relationship. So there is no common structure between polymorphisms.

Applicant then cites previous USPTO policy that "ten sequences constitute a reasonable number for examination purposes. However, new policy was recently instituted at the USPTO to restrict searches to one sequence per group (see Official Gazette article of February 22, 2007 that rescinds the partial waiver of restriction

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practice for sequences that allowed up to ten sequences per application in the 1996 ruling). For examination purposes, only one sequence will be searched in each group since this, for the reasons presented above, places an undue burden on the Examiner and Office resources since a search in multiple expansive databases is required for every sequence. Since only one sequence among the group of SEQ ID NOS. 19473-21982 and one sequence among the group of SEQ ID NOS. 24493-64886 is required to perform the invention according to claims 1 and 23, the election of SEQ ID NOS. 21645 and 61201 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

2. Neither Table 1A nor Table 1B appears in the written version or disc version of the Specification.

### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-7, 14-16, 23-28 and 33-38 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well-established utility.

The current claims are drawn to a method for inferring a trait of a bovine subject from a nucleic acid sample of the subject, comprising identifying at least one occurrence of at least one single nucleotide polymorphism (SNP) corresponding to position 300 of

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SEQ ID NO. 21645, wherein the SNP is associated with the trait, thereby inferring the trait.

**Credible Utility**

Applicants assert on page 10, paragraph 27, of the Specification that the invention provides a method to draw an inference of a trait of a bovine subject by determining the nucleotide occurrence of at least one SNP corresponding to position 300 of the polynucleotide of SEQ ID NO. 21645. There is implied assertion in the Specification that the method is useful to draw inference regarding traits such as thickness, retail yield, marbling, average daily gain and tenderness (elected as species in claims 6 and 37). There is no implied assertion to a specific trait in base claims 1, 23 or 33. The Specification teaches ranking bovine animals for a particular trait wherein each SNP is associated with one or more of these traits that allows animals to be placed in percentiles such as "high" or "low" for a particular phenotypic measurement based on a numeric ranking of the trait (paragraphs 56 and 57). This data is stated to appear in Tables 1A and 1B. However, neither table appears in the written version or disc version of the Specification. Regardless of the missing data, since the base claims do not recite specific traits, there is no inferred utility for the cited SNPs.

Upon identification of credible utilities, the next issue is whether there are any well-established utilities for the method. No well-established utilities for the specific SNP corresponding to position 300 of the polynucleotide of SEQ ID NO. 21645 are identified in either the Specification or in the cited prior art.

**Substantial utility**

Given the absence of a well established utility, the next issue is whether substantial utilities are disclosed in the Specification. Here, the evidence in the Specification provided is that each SNP is associated with one or more traits based on data collected from 3791 bovine animals. Statistically significant associations between specific SNPs and targeted traits were identified utilizing a high density genetic SNP map and the effect of the associated SNP on the target trait through allele frequency differences in the SNP was determined (paragraph 54). This data allows the animals to be placed in percentiles such as "high" or "low" for a particular phenotypic measurement based on a numeric ranking of the trait (paragraph 57). This data is stated to appear in Tables 1A and 1B. However, neither table appears in the written version or disc version of the Specification.

Without data to support the inferred utility of the methods, there is no evidence to suggest that association of a specific SNP and a phenotypic trait is statistically significant. Furthermore, there is no evidence that the association was reproducible. From the limited data presented in the specification, there is no experimental support to indicate how many subjects were used for each SNP or trait. Such a result from a small number of subjects would not support any utility because even if the SNP was associated with one trait in a small number of subjects, there would be no expectation that the result would appear in all subjects with the same SNP.

#### **Specific Utility**

In the current case, even if the substantial utility argument above were found unpersuasive, there is no specific utility given for the SNP cited in claims 1-7, 14-16, 23-

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28 and 33-38. The SNP is not associated with a specific trait and therefore the claims only provide a method for determining a SNP in a sample with no particular association. As the utility guideline training materials note on page 5-6, "Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed". Here, there is no valid disclosure of any condition or "trait" which can be diagnosed or inferred and hence, no specific utility.

***Claim Rejections - 35 USC § 112 – Enablement***

5. Claims 1-7, 14-16, 23-28 and 33-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention



The claims are drawn to methods for inferring a trait of a bovine subject from a nucleic acid sample comprising identifying at least one nucleotide occurrence of a SNP at position 300 of SEQ ID NO: 21645, wherein such a polymorphism is associated with the trait of bovine meat tenderness. The invention is in the class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

#### The breadth of the claims

The claims are broadly drawn to encompass a method for identifying a SNP at position 300 of SEQ ID NO: 21645 associated with the trait of tenderness by contacting the sample with an oligonucleotide that binds to a target region of SEQ ID NO: 61201, wherein the target region comprises a position corresponding to position 300 of SEQ ID NO: 21645 or wherein the target region is within 500,000 nucleotides of this position, and determining the nucleotide occurrence of a SNP at this position by analyzing binding of the oligonucleotide or detecting an amplification product generated using the oligonucleotide.

#### Quantity of Experimentation

The quantity of experimentation in this area is very large since there is significant variability in the effects of polymorphisms on phenotypes such as bovine meat tenderness. Screening each possible polymorphism in the bovine genome represents an inventive, unpredictable and difficult undertaking in itself. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The unpredictability of the art and the state of the prior art

The art is replete with evidence that gene association studies are typically wrong. In fact, Lucentini et al (The Scientist (2004) Vol 18) titled his article "Gene Association Studies Typically Wrong" and states "Two recent studies found that typically, when a finding is first published linking a given gene with a complex disease, there is only roughly a one-third chance that studies will reliably confirm the finding (see page 2 of printout)." This is consistent with the teaching of Wacholder et al (J. Natl. Cancer Institute (2004) 96(6):434-442) who notes that "Too many reports of associations between genetic variants and common cancer sites and other complex diseases are false positives (see abstract). Ioannidis (Nature genetics (2001) 29:306-309) further supports this conclusion in pointing out the heterogeneity of results among different studies of genetic polymorphisms (see abstract, for example).

Even the art associated with identifying bovine SNP markers for trait characterization demonstrates the unpredictability of polymorphism association. Heaton et al. ("Selection and use of SNP markers for animal identification and paternity analysis in U.S. beef cattle," Mammalian Genome, 2002, Vol.13, pp.272-281) state that SNP markers and can be used for association mapping to identify chromosomal regions containing loci involved with phenotypic traits and has been advocated as a method for mapping, however, a significant problem is the potential for spurious associations (i.e. false positives) that arise from unrecognized population stratification or recent admixture (page 279, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph). Heaton also states that at least 34 SNPs would

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be required to identify all 270,000 cattle registered by the American Angus Association, 40 SNPs for all of the 100 million cattle in the U.S., and 43 SNPs would be required for all of the 10 million cattle ever registered by the American Angus Association.

Therefore, it is highly unpredictable whether some currently unknown polymorphism in the bovine genome would have any association with any phenotype. Furthermore, one SNP cannot be used solely to identify a particular phenotype or genotype.

#### Working Examples

The Specification has three working examples. Example 2 reviews data of Tables 1A and 1B (not found in application submission) identifying SNPs associated with one or more traits based on high density SNP maps. In Example 3, Tables 2-4 represent disequilibrium analysis in relation to SNP distance from three different SNPs. In Table 2, SNPs MMBT13976, MMBT09532, and MMBT09533 are shown to be within 500,000 nucleotides of SNP marker MMBT22302 and all show significant association to average daily gain. There is no data corresponding to their significance levels for association of the particular trait and there are only 4-5 SNPs stated to be correlated with such a trait. Furthermore, there is no reference as to where these sequences correspond to the bovine genome in order to determine the distance and position of each sequence and corresponding SNP to each other. The sequences are related to particular "contigs" wherein the Specification does not indicate where in the bovine genome such contigs are located and where they are located with respect to each other. Tables 3 and 4 also show similar patterns for each associated polymorphism.

Guidance in the Specification.

The Specification does not provide sufficient evidence to demonstrate the association of any polymorphism being associated with a particular trait, nor does it provide any significant linkage equilibrium data for the polymorphisms for mapping. The Specification shows a total of 2,510 polymorphisms associated with one or more traits, however it does not provide any statistical data which shows their significance to such traits, or to each other for mapping. The Specification only states that SNP occurrences listed in Tables 1A and 1B (not found in application submission) as associated with a "high" trait characteristic are likely to be associated with a value greater than 50<sup>th</sup> percentile of the bovine population for the relevant trait, and those with a "low" trait are likely to be associated with a value less than 50<sup>th</sup> percentile of the bovine population for the relevant trait (page 21, [0060]); therefore, a SNP associated with 49% of a bovine population for a particular trait is deemed a low trait characteristic SNP, but a SNP associated with 51% of a bovine population for a different trait is deemed a high trait characteristic SNP. The significance data for applicant's elected polymorphism, MMBT05224, i.e. position 300 (a/c) in SEQ ID NO: 21645 cannot be determined since Tables 1A and 1B are not present in the application.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, the level of unpredictability and the teaching gene association studies are highly unpredictable as demonstrated by Heaton, Lucentini, Wacholder and Ioannidis. The specification provides one with no written

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description or guidance that leads one to a reliable method where any polymorphism will be associated with a particular trait, or could be used together for trait mapping. One of skill in the art cannot readily anticipate the effect of a change within the subject matter to which the claimed invention pertains. Furthermore, the Specification does not provide guidance to overcome art and specification recognized problems in the use of polymorphisms for phenotype identification and trait mapping as broadly claimed. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the Specification, the presence of working examples which do not address the full scope of the claims at issue and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the Examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Akhter et al. (GenBank Accession No. AC092085 (2002)).

Akhter teaches a method for inferring a trait of a bovine subject from a nucleic acid sample of the bovine subject, comprising identifying in the nucleic acid sample, at

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least one nucleotide occurrence of at least one single nucleotide polymorphism (SNP) corresponding to position 300 of SEQ ID NO: 21645 (the bovine clone RP42-360C18 was sequenced and reveals an "a/t" nucleotide at position 97781 corresponding to position 300 of SEQ ID NO. 21645, matching the "a" nucleotide that represents one of the two (m= "a" or "g") possible SNPs at this position).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2-7, 14-16, 23-28 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akhter et al. (GenBank Accession No. AC092085 (2002) in view of Cai et al. (U.S. Patent No. 2004/0018511).

Akhter teaches the limitations of claim 1 as discussed above.

With regard to claims 2-7, 14-16, 23-28 and 33-38, Akhter teaches a method for determining a nucleotide occurrence of a polymorphism in a bovine sample, comprising:

a) contacting a bovine polynucleotide in the sample with an oligonucleotide that binds to a target region of at least 20 contiguous bases of SEQ ID NOS: 21645 and 61201, wherein the target region comprises a position corresponding to position 300 of SEQ ID NO: 21645 or wherein the target region is within 3000 or within 500,000 nucleotides of a nucleotide corresponding to this position (the bovine clone RP42-360C18 was sequenced and reveals an "a/t" nucleotide at position 97781 corresponding to position 300 of SEQ ID NO. 21645, matching the "a" nucleotide that represents one of the two (m= "a" or "g") possible SNPs at this position; the sequencing required an oligonucleotide primer, see nucleotide sequence of clone, particularly in the region surrounding 97781 which is homologous to SEQ ID NO. 21645 and 61201 for at least 20 contiguous nucleotides) and

b) determining the nucleotide occurrence of a SNP corresponding to position 300 of SEQ ID NO: 21645 (the bovine clone RP42-360C18 was sequenced and reveals an "a/t" nucleotide at position 97781 corresponding to position 300 of SEQ ID NO. 21645, matching the "a" nucleotide that represents one of the two (m= "a" or "g") possible SNPs at this position).

Akhter does not teach a method wherein the nucleotide occurrence of at least two SNPs is determined to infer a trait, wherein the SNPs comprise a haplotype allele or pairs of alleles related by dominance. Akhter also does not teach SNPs that infer a trait such as tenderness. Akhter also does not teach a method wherein the determination

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comprises analyzing binding of the oligonucleotide or detecting an amplification product generated using the oligonucleotides or a pair of labeled oligonucleotide primers wherein the terminal nucleotide of the oligonucleotide binds to the SNP, thereby determining the nucleotide occurrence of the polymorphism in the test SNP that is in disequilibrium with a SNP corresponding to position 300 of SEQ ID NO. 21645.

Cai teaches methods of identifying genetic polymorphisms, markers and haplotypes such as SNPs associated with bovine traits for the quality of meat such as increased or decreased marbling and meat tenderness (paragraph 16, lines 18-21, paragraph 17, lines 1-7 and paragraph 62, lines 1-22), including identification of two or more SNPs that infer a trait (paragraph 17, lines 7-20), wherein the SNPs may be related by dominance or may show additive gene action, or there may be interlocus interaction (paragraph 238, lines 1-17). Cai also teaches a method for detecting SNPs comprising obtaining a sample from a bovine individual and identifying the SNP by techniques including DNA sequencing, DNA amplification such as PCR, allele specific primer extension and mismatch hybridization (paragraph 20, lines 1-24). For detection by PCR, Cai also teaches primers that hybridize to form a DNA:primer hybrid only if the target sequence is present in a sample (paragraph 121, lines 1-5) and also teaches primer extension reactions requiring a base-paired 3' terminus (paragraph 103, lines 1-24). Primers can be prepared with detectable labels such as fluorescent labels, ligands and antibodies (paragraph 115, lines 1-17).

Cai does not teach a method for inferring a trait of a bovine subject comprising identifying the occurrence of a SNP at position 300 of SEQ ID NO: 21645. Cai also



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does not teach a method for inferring a trait of a bovine subject comprising contacting a bovine polynucleotide with an oligonucleotide that binds to a target region of SEQ ID NO: 61201, wherein the target region comprises a position corresponding to position 300 of SEQ ID NO: 21645 or wherein the target region is within 3000 or within 500,000 nucleotides of this position.

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to combine the method of Akhter for determining the sequence of a bovine sample that includes the sequence surrounding and including position 300 of SEQ ID NO: 21645 with the method of Cai for detecting SNPs in bovine samples that infer traits for the quality of meat such as marbling and meat tenderness since Akhter provides the necessary sequence information SEQ ID NOS: 21645 and 61201 to use the methods of Cai to design oligonucleotides and labeled primers for detection or amplification of the nucleic acid target containing the SNP at position 300, in addition to other SNPs that may be associated with the trait. Thus, an ordinary practitioner would have been motivated to use the SNP sequence information of bovine polynucleotides of Akhter to design reagents for detection of SNPs that infer economically important traits for quality of meat in a bovine subject such as increased or decreased marbling and meat tenderness. Detection of such markers and haplotypes such as SNPs is important for predicting the breeding characteristics of livestock progeny and to optimize the management and marketing of livestock for improving feedlot performance and meat quality (Cai, paragraph 16, lines 7-11).

**Conclusion**

11. Claims 1-28 and 33-38 are rejected. No claims are allowable.

**Correspondence**

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320 and whose fax number is 571-273-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*David C. Thomas 9/27/07*

David C. Thomas  
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Art Unit 1637

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